

## Fields to Capture Adverse Event Data (Draft)

|     | Field  | Definition  |
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| 1.  | Protocol ID                                    | The unique alphanumeric identifier assigned to a protocol by the center.  |
| 2.  | Participant ID                                 | The alphanumeric identifier assigned to the participant by the center, unique within a study.   |
| 3.  | Disease Code                                   | The code to represent at a summary level the category of disease treated on a protocol (Cancer, AIDS, Benign disease), which the participant has. |
| 4.  | Subgroup Code                                  | A code for the unique participant characteristic utilized to uniformly group patients into strata for separate analysis or treatment.             |
| 5.  | Prior Chemotherapy Regimens                    | The previous chemotherapeutic regimens the participant has received.  |
| 6.  | Treating Institution ID                        | The unique alphanumeric identifier for the center.  |
| 7.  | Treatment On Study                             | The treatment as specified by the protocol.   |
| 8.  | Off Treatment Reason                           | The reason why participant was not on the treatment specified by the protocol.  |
| 9.  | Last Treatment Date                            | The date on which the participant last took or was administered the agent(s) of the treatment specified by the protocol.                          |
| 10. | Off Study Reason                               | The reason why participant was removed from the study.  |
| 11. | Therapy Code                                   | A code that specifies the type of systemic therapy the patient received.  |
| 12. | Treatment Assignment Code                      | A code that is a unique identification for each arm or dose level of the protocol.<br>Example: Drug ###mg / m2 IV over X hr D1-3 / every 3 weeks) |
| 13. | Agent ID                                       | The code for the treatment agent.   |
| 14. | Concomitant medication                         | Non-protocol medication that the participant was receiving.   |
| 15. | Baseline Abnormalities Flag                    | A flag to denote if the participant has any baseline abnormalities.   |
| 16. | Baseline AE Type Code                          | The code for the baseline AE's type.  |
| 17. | Baseline AE Grade Code                         | The code for the severity grade of the baseline AE as defined in CTCAE v3.0 with a permissible value of 0 to 5.                                   |
| 18. | Baseline AE Other Specify                      | A baseline AE for which a type code has not been assigned.  |
| 19. | AE Experienced                                 | A flag to denote if the participant experienced AE.   |
| 20. | Preliminary AE Type Code                       | The code for the current AE's type, in the preliminary evaluation.  |
| 21. | Preliminary Unspecified AE (AE Other, Specify) | A current AE for which a type code has not been assigned, in the preliminary evaluation.  |

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| 22. | Preliminary AE Grade Code                | The code for the severity grade of the current AE as defined in CTCAE v3.0 with a permissible value of 0 to 5, in the preliminary evaluation. |
| 23. | Preliminary AE Attribution Code          | The code that indicates which agent or device is the AE (possibly) due to, in the preliminary evaluation.                                     |
| 24. | Final AE Type Code                       | The code for the current AE's type, in the final evaluation.  |
| 25. | Final Unspecified AE (AE Other, Specify) | A current AE for which a type code has not been assigned, in the final evaluation.  |
| 26. | Final AE Grade Code                      | The code for the severity grade of the current AE as defined in CTCAE v3.0 with a permissible value of 0 to 5, in the final evaluation.       |
| 27. | Final AE Attribution Code                | The code that indicates which agent or device is the AE (possibly) due to, in the final evaluation.   |
| 28. | Other contributing cause                 | A secondary factor that contributed to the current AE.  |
| 29. | AE expected                              | A flag to indicate If the experienced AE was expected   |
| 30. | AE Report Filed                          | A flag to indicate if the AE report has been filed.   |
| 31. | Late AE Type Code                        | The code for the late AE's type.  |
| 32. | Late AE Grade Code                       | The code for the severity grade of the late AE as defined in CTCAE v3.0 with a permissible value of 0 to 5.                                   |
| 33. | Late Unspecified AE (AE Other, Specify)  | A late AE for which a type code has not been assigned.  |
| 34. | Late AE Start Date                       | The date on which the late AE started   |
| 35. | Gen AE Comments                          | Comments about the current AE.  |
| 36. | Present Status Code                      | The code indicating the present status of the participant   |
| 37. | Submission Date                          | Date of submission of AE report   |
| 38. | Completer Name                           | The name of the person who updated any of the data in the report and is responsible for the data entered                                      |
| 39. | Completer Phone                          | The primary telephone number for contacting the person who updated any of the data in the report and is responsible for the data entered      |
| 40. | Completer Fax                            | The fax number of the person who updated any of the data in the report and is responsible for the data entered                                |
| 41. | Completer Email                          | The email address of the person who updated any of the data in the report and is responsible for the data entered                             |